DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

97657d

OCT 30 2002

VIA FEDERAL EXPRESS

WARNING LETTER

James Nabors, Product Support Manager and
Acting Radiation Safety Officer
Heimann Systems Corporation
3143 Regal Drive
Alcoa, Tennessee 37701

Ref:OC:I1-1927

Dear Mr. Nabors:

This letter is written to advise you of items of noncompliance with the federal radiation safety performance standard for cabinet x-ray systems (21 CFR 1020.40) encountered during a field test of a Heimann Systems Corporation model HS 6030 di cabinet x-ray system. The system was tested on August 9, 2002. It was manufactured May of 2002 and has serial number 24147. This system is installed in the lobby of a Food and Drug Administration (FDA) office building located at 2094 Gaither Road, Rockville, MD 20850. Additionally, this letter acknowledges receipt of your letter, dated September 12, 2002, responding to telephone conversations on the field test results.

1. 21 CFR 1020.40(c)(3)(i) requires that the insertion of any part of the human body through any port into the primary beam shall not be possible. We observed that it is possible for part of the human body to be easily inserted into the primary x-ray beam. Our measurements indicated that the side of the cabinet is 38 inches long, the top of the cabinet is 36 inches long, the lead curtain is 1 inch inside the plane of the port as defined by the top of the cabinet, and the primary beam is located 17 inches from the lead curtain.

   Your September 12, 2002 letter states that a response to this item is being prepared.

2. 21 CFR 1020.40(c)(10) requires that x-ray systems designed for security screening of carried possessions in public facilities shall be provided with means to insure operator presence at the control area in a position which permits surveillance of the ports during generation of x-radiation. We observed that this system was installed in a public area of an office building and did not require the operator to be present to produce x-rays. The conveyor forward and backward buttons could be pressed once and the

conveyor would continue to operate. This allowed x-ray generation to take place when an object was placed on the conveyor and passed through the system even with no one present.

Your September 12, 2002 letter indicates that this problem is also under investigation and lists four possible means to comply with this requirment. Future responses to this letter should address specific actions that will be taken to assure that all systems currently installed in public areas have some means enabled, and also the actions taken to assure that new systems installed in a public area will always be installed with some means enabled.

3. 21 CFR 1020.40(c)(6)(iii) requires that x-ray on indicators that are not milliammeters be legibly labeled, "X-RAY ON." We observed that the pair of what appeared to be x-ray on indicator lights on the control panel were not labeled with the words, "X-RAY ON."

   Your September 12, 2002 letter acknowledges this noncompliance and states the x-ray on indicators will be labeled appropriately. Your response to this letter must confirm that your "application for modification" was approved by your German offices and provide additional detail on how the correction will be implemented.

4. 21 CFR 1010.3(a)(2)(ii) requires that the identification label displays the month of manufacture spelled out in English. The month of manufacture was spelled "Mai" on the identification label.

   Your September 12, 2002 letter does not address this noncompliance.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce cabinet x-ray system products, which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The FDA is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 working days of receipt of this letter. Your response should pursue one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation – You may submit your views and evidence to establish that the alleged failures to comply do not exist in accordance with 21 CFR 1003.11(a)(3).

2. Exemption Request – You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action – If you neither refute the noncompliance nor request an exemption, then you will be required to: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

    a. Notification Letter – Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

    b. Corrective Action Plan – Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following failure to comply with the regulations regarding reports and record keeping was observed:

1. 21 CFR 1002.10 or 1002.11, no product report or supplement has been submitted for a model HS 6030 di cabinet x-ray system.

    Your September 12, 2002 letter does not address this noncompliance.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, Nashville District Office, Food and Drug Administration, 297 Plus Park

Blvd. (HFR-SE340), Nashville, Tennessee 37217. If you have further questions on these requirements, please contact Daniel Kassiday of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Gladys Rodriguez

for Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health